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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,277	06/08/2006	Friedhelm Brassel	13455/1	6606

26646 7590 05/16/2008

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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
05/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,277	BRASSEL, FRIEDHELM	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☒ Claim(s) *4-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending and under examination.

Comments:

1) On page 1 line 1 of the specification, the 371 data should be inserted.

2) Independent claims should begin with --- A ---; such as, A liquid embolizate.... and dependent claims should begin with --- The ---; such as, The liquid embolizate...

Please correct.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

Claims 4-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

As a courtesy to Applicant and in the interest of compact prosecution, the Examiner will point out clear 35 U.S.C. 112 problems in the objected claims though the art will only be applied to claims 1-3.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner if the % v/v of (a), (b) and (c) represent the amounts of the components in the final mixture or are the % v/v of the components before mixing. Please clarify the claim language. The claims will be examined as they read on % v/v of the final mixture.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 contains the trademark/trade names Ethibloc and Lipiodol. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe components (a) and (b) and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 112

The following are quotations of 35 U.S.C. §§ 101 and 112, second paragraph, respectively, which form the basis of the claim rejections as set forth under this particular section of the Official Action:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 14 recite “Application” which the Examiner is interpreting to mean “use”.

Claims 13 and 14 provides for the use of the embolizate, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13 and 14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

As a result, the Applicants are respectfully required to redraft the aforementioned use claims as statutory process claims that delimit active, positive steps on how to use a composition according to the invention as originally filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doerfler et al. (Neuroradiology 2001, 43, 1112-1117).

Applicant claims a liquid embolizate.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Doerfler et al. teach Ethibloc (60% ethanolic zein) and Lipiodol compositions in ratios of E/L 1:1, 1:2 and 1:3) (Abstract and page 1113, table 1 and Ethibloc right column). Doerfler et al. teach injection through a microcatheter is not smooth because of Ethibloc's high viscosity and to decrease the viscosity by mixing with the oily contrast medium Lipiodol (page 1113, right column Ethibloc). Methods of mixing Ethibloc in 3-way tap with Lipiodol (page 1113, study design). Doerfler et al. teach that the high viscosity of Ethibloc can become a problem with certain microcatheters which rupture while the embolic agent is injected (page 1115, lower right paragraph through page 1116).

Doerfler et al. establish two things: 1) Ethibloc is highly viscous and 2) Lipiodol is a known contrast medium in liquid form.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Doerfler et al. is that Doerfler et al. do not expressly teach diluting Ethibloc with more ethanol.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add more ethanol to the composition of Doerfler et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Doerfler et al. teaches that the compositions are highly viscous and rupture certain catheters and injections are not smooth. To improve injection smoothness and decrease viscosity it is obvious to add solvent. Ethibloc comes as an ethanolic solution. It would be obvious to add more ethanol since ethanol is the solvent. Volume ratios of between 1:2 and 2:1 for components (b) and (c) and 15-35 % v/v of components (b) and (c) and 30-70 % v/v of (a) are easily obtained by optimization of the amount of solvent in the absence of evidence to the contrary. It is merely ordinary innovation to add more ethanol solvent to decrease the viscosity. The expected and predictable result is a less

viscous solution of Ethibloc. From recent case law: "the results of ordinary innovation are not the subject of exclusive rights under the patent laws." (KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. 550 U. S. ____ (2007) page 24).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Doerfler et al. (Neuroradiology 2001, 43, 1112-1117) in view of Mottu et al. (Biomaterials, 2000, 21, 803-811).

Applicant claims a liquid embolizate.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Doerfler et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Mottu et al. teach water-miscible solvents for embolic liquids which include ethanol (Table 2, page 805).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Doerfler et al. is that Doerfler et al. do not expressly teach diluting Ethibloc with more ethanol. This deficiency in Doerfler et al. is cured by the teachings of Mottu et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add more ethanol to the composition of Doerfler et al., as suggested by Mottu et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Doerfler et al. teaches that the Ethibloc embolic compositions are highly viscous and rupture certain catheters and injections are not smooth. One of ordinary skill in the art would have looked for means to decrease the viscosity of the embolic composition of Doerfler et al. and used ethanol, as suggested by Mottu et al., to dilute the embolic liquid. Volume ratios of between 1:2 and 2:1 for components (b) and (c) and 15-35 % v/v of components (b) and (c) and 30-70 % v/v of (a) are easily obtained by optimization of the amount of solvent in the absence of evidence to the contrary. It is merely ordinary innovation to add more ethanol solvent to decrease the viscosity. The expected and predictable result is a less viscous solution of Ethibloc. From recent case law: "the results of ordinary innovation are not the subject of exclusive rights under the patent laws." (KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. 550 U. S. ____ (2007) page 24).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ren (US 2002/0115904) teaches in claim 2:

> 2. A settable, magnetically guideable embolic material for occluding vascular defects, the material comprising:
>
> between about 6 weight percent and about 20 weight percent prolamine
>
> between about 16 weight percent and about 50 weight percent ethanol
>
> between about 20 weight percent and about 60 weight percent magnetically responsive material;
>
> between about 5 and about 35 percent of a radio-opaque material.

Dubois et al. (Pediatr Radiol 2003, 33, 365-372) teach diluting Ethibloc with 100% ethanol (page 368, left column).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Examiner, Art Unit 1616
Technology Center 1600